Multi-center, single-arm study to assess the safety, efficacy, discontinuation rate and pharmacokinetics of the low-dose levonorgestrel intrauterine contraceptive system (LCS12) in post-menarcheal female adolescents under 18 years of age for 1 year, and an optional 2-year extension phase

Published: 28-07-2011
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The study will assess the safety of a sex hormone (levonorgestrel) releasing T-shaped intrauterine contraceptive system in female adolescents under 18 years of age. The incidence of adverse events over 12 month treatment period will be the main...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40073

Source
ToetsingOnline

Brief title
LCS12 adolescent study

Condition

- Other condition

Synonym
intrauterine system as a contraceptive, prevention of pregnancy

Health condition

intrauterine anticonceptie

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer Healthcare AG

Intervention

Keyword: adolescent, contraception, intrauterine

Outcome measures

Primary outcome

1) Number of adverse events reported by study subjects 2) Portion of subjects

reporting adverse events

Secondary outcome

1) Overall satisfaction rating from 1 to 5 (from very satisfied to very

dissatisfied)

2) Pearl Index

3) Bleeding patterns collected from patients' diary

4) Concentration of levonorgestrel in serum

5) Concentration of sex hormone binding globulin in serum

6) Discontinuation rate

Study description

Background summary

Safety of LCS12 in adolescents according to by EMA approved Paediatric Investigational Plan

Study objective

The study will assess the safety of a sex hormone (levonorgestrel) releasing T-shaped intrauterine contraceptive system in female adolescents under 18 years of age. The incidence of adverse events over 12 month treatment period will be the main outcome of this study. Also the efficacy (number of pregnancies), discontinuation rate and pharmacokinetics will be evaluated.

Study design

Non-exploratory trial

Intervention

LCS12 insertion into the uterus at insertion visit 2 with the study treatment of 12 months. An optional follow up phase up to 2 years will be offered for all subjects completing 12 month treatment time.

Study burden and risks

Risk to be find at section E9.
Burden: 7-9 visits, daily completion of an electronic diary during the first year, blood (max 4) and urine samples (7-9) and cervical smear (once). Gynaecologic examination, including breast palpitation (7-9 times) and a general physical examination (2-4 times)

Contacts

Public
Bayer

Energieweg 1
Mijdrecht 3641 RT
NL
Scientific
Bayer

Energieweg 1
Mijdrecht 3641 RT
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

- The subject has signed and dated the informed consent form.
- The subject is a female adolescent, generally healthy, post-menarcheal, nulliparous or parous requiring contraception and is under 18 years of age at screening visit.
- The subject has regular menstrual cycles without hormonal contraceptive use (at regular intervals of 21-35 days).
- In the opinion of the investigator, the subject has general and uterine conditions suitable for the insertion of LCS12 (uterine sound depth 6-10cm).
- The subject has clinically normal safety laboratory results.
- The subject has a normal or clinically insignificant cervical smear (i.e. one that does not require further follow up according to Bethesda or a comparable system).
- The subject is willing and able to attend the scheduled study visits and to comply with the study procedures

Exclusion criteria

- Known or suspected pregnancy or is lactating.
- Vaginal delivery, cesarean delivery, or abortion less than 6 weeks before Visit 1.
- Historic of ectopic pregnancies.
- Infected abortion or postpartum endometritis less than 3 months before Visit 1.
- Abnormal uterine bleeding of unknown origin.
- Any lower genital tract infection (until successfully treated).
- Acute or history of recurrent pelvic inflammatory disease.
- Congenital or acquired uterine anomaly.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2011
Enrollment:	96
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	LCS12
Generic name:	nvt

Ethics review

Approved WMO

Date:	28-07-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	12-09-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	01-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	25-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-09-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-09-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-002065-37-NL
CCMO	NL37467.060.11